K072680

OCT 25 2007

510(k) Summary

Drystar AXYS

Common/Classification Name: Medical Image Hard Copy Device
21 CFR 892.2040

Sponsor:

Agfa Healthcare Corporation
10 South Academy Street
Greenville, SC 29601

Contact:

Patrick Lynch
Agfa Healthcare Corporation
10 South Academy Street
Greenville, SC 29601

Prepared: September 19, 2007

A. Legally Marketed Predicate Devices.

The Drystar 5500 printer is legally marketed (cleared) under 510(k) number K023287. The new Drystar AXYS, the subject of the present 510(k), is very similar to the cleared Drystar 5500 in both hardware and software. From the point of view of the hardware and software, the Drystar AXYS is substantially equivalent to the Drystar 5500. From the point of view of the intended use of the device, dry printing general radiology and mammography images on film, the device is substantially equivalent to the Drystar 5500.

B. Device Description.

The device is the new Drystar AXYS and it is a dry, B/W printer, using the direct thermal printing principle to produce continuous-tone images with medical diagnostic image quality onto plastic sheets which can be viewed on a light box. The printer is sold with two film input trays. Each tray can be adjusted to five different sizes (in inches) of film, including 8x10, 10x12, 11x14, 14x14 and 14x17. Three different types of film can be used in this new device, two for general purpose radiography and a new type of film for mammography, Drystar DT 2 M.

The new mammography film comes in only two sizes 8x10 and 10x12. It is thicker than the general purpose radiography film in order to provide a wider

range of optical densities. The printer also handles borders for mammography images in a different manner than for regular medical images.

C. Intended Use.

The Drystar AXYS is a free-standing dry film printer used to print diagnostic images on transparent film for viewing on a standard view box. It may be used in any situation in which a hard copy of an image generated by a medical imaging device is required or desirable, including digital mammography.

D. Substantial Equivalence Summary.

The new Drystar AXYS has the same indications for use as the cleared Drystar 5500.

The new Drystar AXYS has essentially the same technological characteristics as the cleared Drystar 5500. The differences can be seen in Table 3.1 located in Section III.

This premarket notification has described the characteristics of the Drystar 5500 in sufficient detail to assure a substantial equivalence determination.

E. Technological Characteristics.

The technological characteristics of the new Drystar AXYS are identical to those of the predicate device, the Drystar 5500.

F. Testing

The Drystar AXYS contains an automatic QC procedure that assures compliance with the Mammography Quality Standards Act (MQSA) of the FDA. It was also tested against and met a number of consensus standards for safety and electromagnetic compatibility.

G. Conclusions.

This pre-market submission has demonstrated Substantial Equivalence as defined and understood in Sections 513(f)(1) and 513(I)(1) of the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2007

Mr. Patrick J. Lynch
Manager of Regulatory Affairs
AGFA Healthcare Corporation
10 S. Academy Street, P.O. Box 19048
GREENVILLE SC 29602-9048

Re: K072680
Trade/Device Name: Drystar AXYS
Regulation Number: 21 CFR 892.2040
Regulation Name: Medical image hardcopy device
Regulatory Class: II
Product Code: LMC
Dated: September 19, 2007
Received: September 21, 2007

Dear Mr. Lynch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K072680

Device Name: Drystar AXYS

Indications For Use:

The Drystar AXYS is a free standing device used to print diagnostic conventional and mammography images on transparent film for viewing on a standard view box. It may be used in any situation in which a hard copy of an image generated by a medical imaging device is required or desirable.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072680